DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

m08491

WARNING LETTER - RETURN RECEIPT REQUESTED

AUG 10 1999

Ms. Sharon Easterbrook
or Current Risk Manager
Kaweah Delta District Hospital
400 West Mineral King Ave.
Visalia, California 93291

Dear Ms. Easterbrook:

The Food and Drug Administration (FDA) received a report concerning an infant death associated with your facility. We have enclosed a redacted copy of the report for your information. Because this event involved the use of a medical device, your facility is required to report this death to the FDA under the Medical Device Reporting (MDR) Regulation. (See Title 21, of the Code of Federal Regulations, Part 803).

Section 519(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act (the Act) requires a user facility, (such as your hospital) to submit a report whenever it receives, or otherwise becomes aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility. An MDR report is required as soon as practicable, but no later than 10 working days after becoming aware of the information. Our review of the attached report, and the Valley Children's Hospital investigation of the death, suggests that the fetal vacuum extractor (vacuum assisted delivery device) has or may have caused or contributed to the infant's death.

Your facility should have known that this type of event is reportable to FDA. Prior to this infant's death we issued a Public Health Advisory dated May 21, 1998, concerning the "Need for CAUTION When Using Vacuum Assisted Delivery Devices" (copy enclosed). This advisory clearly described the association of the use of vacuum assisted delivery devices with potentially fatal subgaleal hemorrhage, as well as the requirement for the submission of user facility reports to FDA for any of the complications noted in the advisory. Our records indicate that at least one copy of our Public Health Advisory was sent to your facility.

To date, we have not received an MDR report on this event from your facility. Your facility must immediately report this event to the FDA and the manufacturer of the device using the MedWatch 3500A form (copy enclosed). In addition, we urge you to review your written MDR reporting procedures to determine if changes need to be made to ensure that this type of reporting error does not recur. Furthermore, you must submit a copy of your written/revised MDR procedures to the address listed on this letterhead within 60 days after receipt of this letter.

Your failure to report this event is a serious violation of the Act. In legal terms this means your facility misbranded the device under section 502(t)(2) of the Act when it failed to report the incident in the required timeframe. You need to take prompt action to correct this violation of Federal Law. Your failure to do so could result in enforcement action, without further notice, such as civil money penalties.

Please notify this office, in writing, within 15 working days of your receipt of this letter of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, you must state the reason for the delay and the time within which the correction will be completed. A copy of this letter has been provided to the FDA's San Francisco District Office.

If you have any questions about this letter please contact Mr. John Farnham of the OB/GYN, Gastroenterology, and Urology Branch at (301) 594-4616.

Sincerely yours

Lillian J. Gill
Director
Office of Compliance
Center for Devices
And Radiological Health

Enclosures